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Award Number: DAMD17-99-1-9274

TITLE: A Controlled Study using Acupuncture as an Adjuvant to  
Treat Chemotherapy-Induced Nausea and Vomiting

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REPORT DATE: September 2002

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

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20030317 021

**REPORT DOCUMENTATION PAGE**Form Approved  
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

<b>1. AGENCY USE ONLY (Leave blank)</b>		<b>2. REPORT DATE</b> September 2002	<b>3. REPORT TYPE AND DATES COVERED</b> Final (1 Sep 99 - 31 Aug 02)	
<b>4. TITLE AND SUBTITLE</b> A Controlled Study using Acupuncture as an Adjuvant to Treat Chemotherapy-Induced Nausea and Vomiting			<b>5. FUNDING NUMBERS</b> DAMD17-99-1-9274	
<b>6. AUTHOR(S)</b> Lixing Lao, M.D., Ph.D. Brian Berman, M.D.				
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<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			<b>10. SPONSORING / MONITORING AGENCY REPORT NUMBER</b>	
<b>11. SUPPLEMENTARY NOTES</b> Original contains color plates: All DTIC reproductions will be in black and white.				
<b>12a. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited				<b>12b. DISTRIBUTION CODE</b>
<b>13. ABSTRACT (Maximum 200 Words)</b> Nausea and vomiting (N/V) are significant side effects of cancer chemotherapy. This randomized, double blind controlled study was designed to assess the effects of electroacupuncture (EA) on chemo- induced N/V in breast cancer patients. Seventy-five outpatients were originally designed to be recruited and randomized into three groups (total N=75): 1) 100Hz EA, 2) 10Hz EA, and 3) sham control. 101 patients were screened, 18 judged as eligible, and 10 consented to go on the protocol. Complete data were obtained from the 8 participating patients (100Hz EA, n=3; 10Hz EA, n=2; and sham, n=3). Ages ranged from 35 to 69 years old with a mean (SD) of 49.74 (11.51). The blinding of the treatment assignments was successfully concealed. Although there was no statistical significance was obtained, due to insufficient sample size, the trend showed that 100Hz EA had better antiemetic effects. No statistical significance was found in patients' quality of life. No subjects withdrew and no serious adverse events due to acupuncture treatment were observed. However, the study experienced difficulty with obtaining sufficient numbers of patients, partly due to the low prevalence of N/V among the chemotherapy patients as a result of the effectiveness of new antiemetics such as 5-HT <sub>3</sub> antagonists.				
<b>14. SUBJECT TERMS</b> breast cancer			<b>15. NUMBER OF PAGES</b> 11	
			<b>16. PRICE CODE</b>	
<b>17. SECURITY CLASSIFICATION OF REPORT</b> Unclassified	<b>18. SECURITY CLASSIFICATION OF THIS PAGE</b> Unclassified	<b>19. SECURITY CLASSIFICATION OF ABSTRACT</b> Unclassified	<b>20. LIMITATION OF ABSTRACT</b> Unlimited	

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## INTRODUCTION

Nausea and vomiting (N/V) are significant side effects of cancer chemotherapy which can both affect a patient's quality of life and compromise a physician's ability to deliver adequate doses of effective chemotherapy. The purposes of this study are: 1) to evaluate the effectiveness of electroacupuncture (EA) as an adjunctive therapy for minimizing nausea and vomiting caused by chemotherapy; 2) to compare the effectiveness of two protocols of EA on N/V; and 3) to measure the usefulness of EA in improving the general quality of life of cancer patients. This is a randomized, double blind controlled clinical trial with independent assessment of the effect of EA on nausea and vomiting induced by chemotherapy in patients who do not respond to 5-HT<sub>3</sub> antiemetics. The specific aims of this study are three-fold: 1) to evaluate the usefulness of EA as an adjuvant on N/V in chemotherapy patients who do not respond to 5-HT<sub>3</sub> antiemetics; 2) to compare the effectiveness of two protocols of EA on N/V; and 3) to document the benefit of EA on improving the general quality of life of cancer patients. The protocol called for the randomization of 75 outpatients recruited from the UMB Cancer Center, shown to be refractory to 5-HT<sub>3</sub> antiemetic, into three treatment groups (n=25 per group): treatment group I (EA: 10 Hz, 10 min), treatment group II (EA: 100 Hz, 10 min), and sham control group.

## BODY

101 patients were screened with 18 judged as eligible and 10 consented to participate. These 10 patients have now completed the study. Complete data was obtained from the 8 participating patients. Data from 2 participating patients were not complete and one patient failed to return the seven-day diary. No serious adverse events due to acupuncture treatment have been observed. However, the study has experienced difficulty with obtaining sufficient numbers of patients despite intensive recruiting efforts, partly due to the low prevalence of N/V among the chemotherapy patients at the UMB Cancer Center as a result of the effectiveness of new generation antiemetics such as 5-HT<sub>3</sub> antagonists.

Data from 8 participants (EA 100Hz, n=3; EA 10Hz, n=2; and Sham control, n=3) have been analyzed. Ages ranged from 35 years old to 69 years old with a mean (SD) of 49.74 (11.51). The blinding of the treatment assignments was successfully concealed (Table 1). Although there was no statistical significance obtained among the three groups due to insufficient sample size, the trend showed that 100Hz EA had better antiemetic effects than control with respect to both the number of the vomiting (Fig. 1) and the severity of the nausea (Fig 2). No statistical significance among three groups was found in patients' quality of life (Table 2).

### List of paid personnel in this study:

Dr. Lixing Lao, Principal Investigator  
Dr. Brian Berman, co- Principal Investigator  
Dr. Patricia Langenberg, Statistician  
Dr. Grant Zhang, Acupuncturist (5%)  
Molly Himes, L.Ac., Acupuncturist (5%)  
Dr. Chengsi Yu, Acupuncturist (5%)  
Mary Bahr, Research Coordinator

**Table 1. Effect of EA on Breast Cancer Patients' Quality of Life**

	True acupuncture 100 Hz		True acupuncture 10 Hz		Sham control	
	pre (n=3)	post (n=2)	pre (n=2)	post (n=2)	pre (n=3)	post (n=3)
<b><i>Global Health Status*</i></b>						
Global Health Status	38.89	54.17	16.67	37.50	38.89	44.44
<b><i>Functional Scales*</i></b>						
Social Functioning	38.89	41.67	75.00	75.00	72.22	72.22
Role Functioning	83.33	75.00	100.00	100.00	33.33	66.67
Physical Functioning	86.67	80.00	100.00	90.00	66.67	80.00
Cognitive Functioning	66.67	83.33	100.00	100.00	72.22	77.78
Emotional Functioning	58.33	58.33	87.50	83.33	52.78	58.33
<b><i>Symptom Scales**</i></b>						
Pain	33.33	0.00	25.00	16.67	16.67	27.78
Fatigue	44.44	61.11	27.78	44.44	40.74	48.15
Dyspnoea	33.33	0.00	0.00	0.00	22.22	11.11
Constipation	33.33	66.67	33.33	50.00	55.56	44.44
Appetite Loss	44.44	33.33	33.33	66.67	55.56	44.44
Insomnia	33.33	50.00	16.67	16.67	33.33	33.33

\*Score range from 0 to 100, with a higher score representing a higher level of functioning.

\*\*Score range from 0 to 100, with a higher score representing a greater degree of symptoms.

**Table 2. Results of the Patient Blinding Procedures**

Patient Conjectures	Time of Administration		
	1 <sup>st</sup> Treatment	2 <sup>nd</sup> Treatment	3 <sup>rd</sup> Treatment
	<b>Acupuncture Group</b>		
Belief that they did receive Acupuncture (correct guess)	1 (20%)	2 (40%)	1 (20%)
Uncertain	3 (60%)	2 (40%)	4 (80%)
Belief that they did not receive Acupuncture (incorrect guess)	1 (20%)	1 (20%)	0 (0%)
	<b>Sham Control Group</b>		
Belief that they did receive Acupuncture (incorrect guess)	3 (100%)	3 (100%)	2 (100%)
Uncertain	0 (0%)	0 (0%)	0 (0%)
Belief that they did not receive Acupuncture (correct guess)	0 (0%)	0 (0%)	0 (0%)

**Figure 1. Effect of EA on Chemo-induced Vomiting**

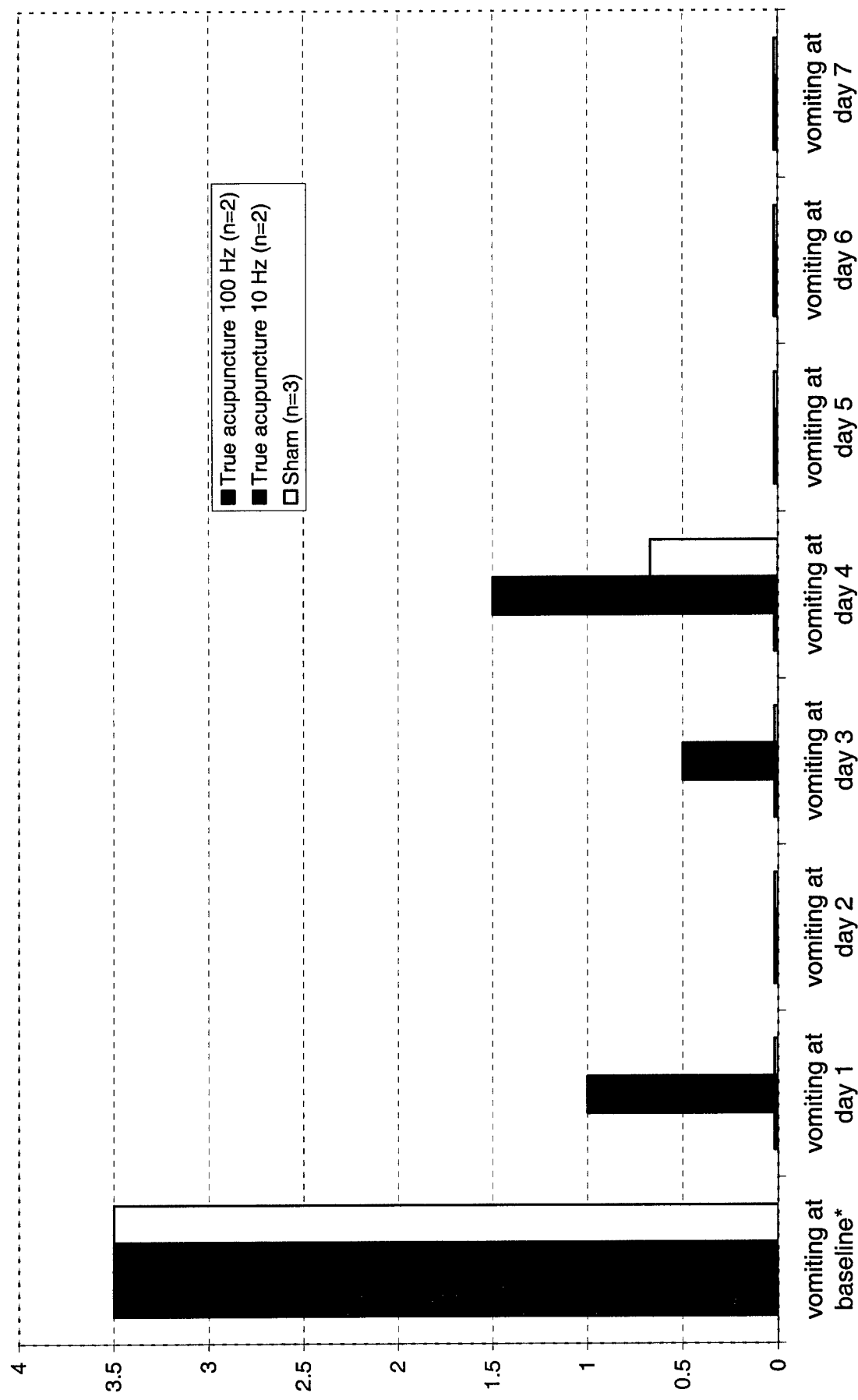


Figure 1. The effect of EA on the episode number of chemotherapy-induced vomiting. \* The number of episode presented at baseline was based on the score of standard World Health Organization (WHO) toxicity criteria at the average of grade 2 level rather than actual scores obtained from the patients.

**Figure 2. Effect of EA on Chemo-induced Nausea**

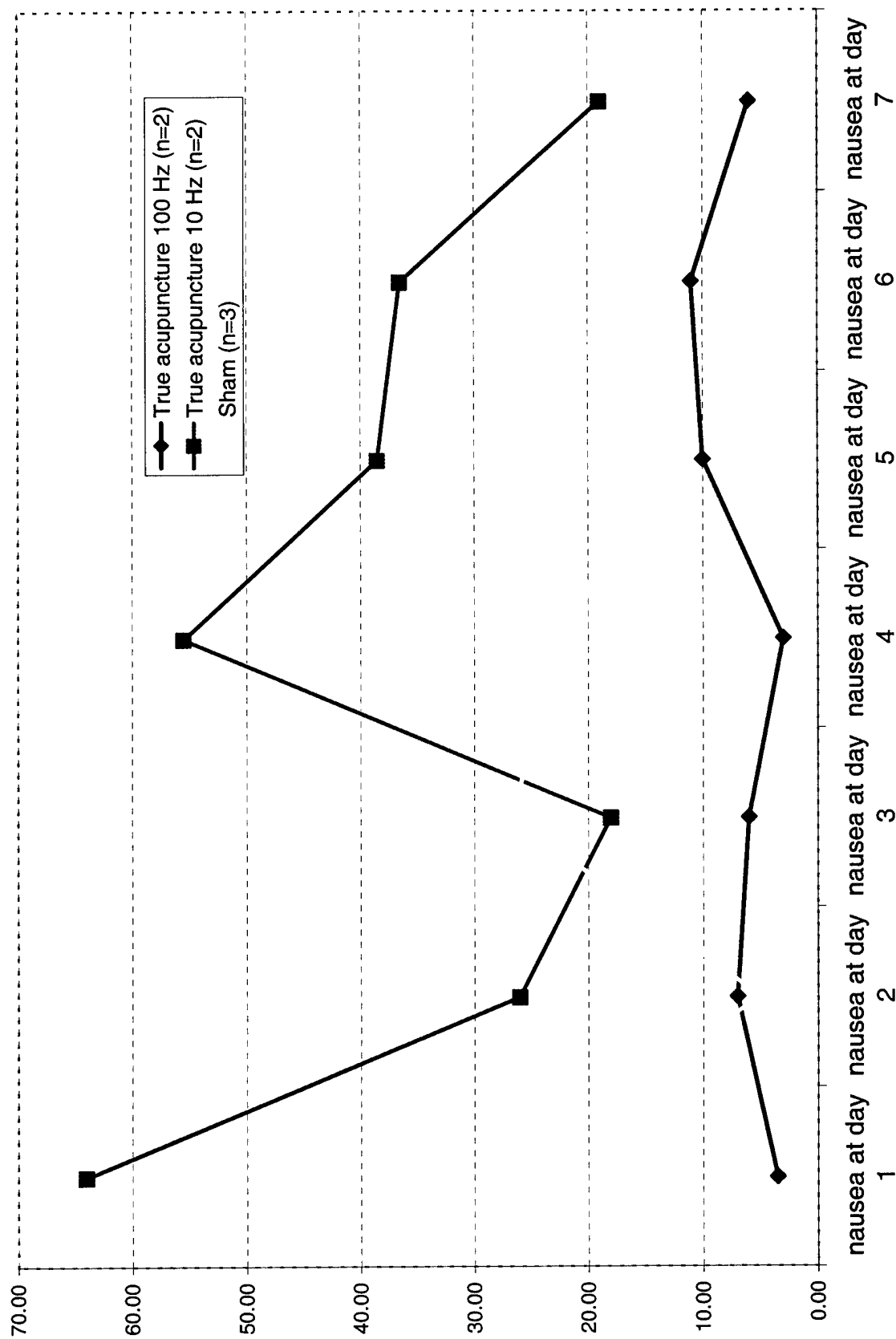


Figure 2. The effect of EA on the severity level of chemotherapy-induced nausea. The scores were comprised of the mean of a patient self-administered visual analogue scale.



## **KEY RESEARCH ACCOMPLISHMENTS**

- Trend showed that 100Hz EA had better antiemetic effects than sham control and 10Hz EA on chemo-induced N/V. The data provided preliminary information for future clinical trials.
- The blinding of the treatment assignments was successfully concealed and the treatment protocol worked well and smoothly.
- No significant adverse events due to acupuncture treatment have been observed or reported.

## **REPORTABLE OUTCOMES:**

- Superiority of 100Hz EA to both sham control and 10Hz EA with respect to antiemetic effects on chemo-induced N/V.
- Data provides preliminary information for power analysis for future clinical trials.
- Validation of a sham procedure not distinguishable from true acupuncture.
- Further evidence provided for the safety of acupuncture within a vulnerable patient population.

## **CONCLUSIONS:**

The new generation antiemetics such as 5-HT<sub>3</sub> antagonists seem to be quite effective, leading to relatively few incidents of N/V in patients receiving chemotherapy. Although no statistically significant differences were obtained among the three groups due to insufficient sample size, a trend showed that 100Hz EA appears to have superior antiemetic effects to 10Hz EA and sham control in controlling N/V. Consistent with other studies of EA treating N/V, our study showed no significant adverse events due to acupuncture treatment.

## REFERENCES:

Lao, L., Bausell, B., Bahr-Robertson, M., Tkaczuk, K., Lee, WL., Berman, B. A Controlled Study Using Acupuncture As An Adjuvant to Treat Chemotherapy-Induced Nausea And Vomiting. *Era of Hope 2002 Department of Defense Breast Cancer Research Program Meeting*. Orlando, Florida (September 25-28, 2002)

*Era of Hope 2002 Department of Defense Breast Cancer Research Program Meeting  
September 25-28, 2002, Orlando, Florida*

## **A CONTROLLED STUDY USING ACUPUNCTURE AS AN ADJUVANT TO TREAT CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING**

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### **ABSTRACT**

Nausea and vomiting (N/V) are significant side effects of cancer chemotherapy that both affect a patient's quality of life and compromise a physician's ability to deliver adequate doses of effective chemotherapy. This was a randomized, double blind controlled study designed to assess the effects of electroacupuncture (EA) on N/V induced by chemotherapy in cancer patients. The primary aim of this study was to evaluate the usefulness of EA as an adjuvant on N/V in chemotherapy patients who did not respond to conventional antiemetics.

Seventy-five outpatients were designed to be recruited from the University of Maryland Baltimore (UMB) Cancer Center (who would have shown refractory to 5-HT<sub>3</sub> antiemetic) and randomized into the following three treatment groups (n=25 per group): (1) EA: 10 Hz, 20 min, (2) EA: 100 Hz, 20 min, and (3) a sham acupuncture control group.

101 patients have been screened, 18 judged as eligible, and 10 have consented to go on the protocol and have now completed the study. Complete data have been obtained from the 8 participating patients and presented. Data from 2 participating patients were not complete. The treatment procedures appear to be working smoothly. No subjects have withdrawn and no serious adverse events due to acupuncture treatment have been observed. However, the study has experienced difficulty with obtaining sufficient numbers of patients despite intensive recruiting efforts, partly due to the low prevalence of N/V among the chemotherapy patients at the UMB Cancer Center as a result of the effectiveness of new antiemetics such as 5-HT<sub>3</sub> antagonists.

Data from 8 participants (EA 100Hz, n=3; EA 10Hz, n=2; and Sham control, n=3) have been analyzed. Ages ranged from 35 years old to 69 years old with a mean (SD) of 49.74 (11.51). The blinding of the treatment assignments was successfully concealed. Although there was no statistical significance was obtained among the three groups, due to insufficient sample size, the trend showed that 100Hz EA had better antiemetic effects than control with respect to both the number of the vomiting and the severity of the nausea. No statistical significance among three groups was found in patients' quality of life.

**Supported by the U.S. Army Medical Research and Materiel Command under DAMD17-99-1-9274.**